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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,346	11/12/2003	Steven F. Bolling	ORQIS.007A	6824

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT PAPER NUMBER

3763

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/706,346	<b>Applicant(s)</b> BOLLING ET AL.	
	<b>Examiner</b> Christopher D. Koharski	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-21 and 86-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21 and 86-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges new claims 86-106, in additions to current claims 1, 3-21, with claims 2 and 22-85 cancelled.

Applicant's arguments are persuasive regarding the withdrawal of claims 7 and 15-20, therefore Examiner withdraws the previous removal of claims 7 and 15-20, currently claims 1, 3-21 and 86-106 are pending for examination in this application.

Examiner's response to Applicant's remarks is found below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 13, 21, 88, 89, 90, 92, 93, 94, 96, 98, 101, 103 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Berry et al. (6,293,958). Berry et al. discloses a catheter having a flow-diffusing tip.

Regarding claims 1, 3-8, 13, 21, 88, 89, 90, 92, 93, 94, 96, 98, 101, 103 and 104, Berry et al. discloses a main cannula portion (10) with a lumen extending through the main body and the tip portion (12) with a redirecting opening that allows for discharge of a material proximal to the catheter body (Figure 1). The plurality of openings can be closed and opened upon insertion that has a predefined shape and structure (Figure 1) are expandable. The openings are spaced radially around the tip portion and are

configured to redirect the flow through the lumen of the catheter proximally (Figure 1). During operation and during insertion the surface of the expandable members (16, 18) are capable of forming spherical or parabolic curved surfaces when being flexed (Figure 1).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Shmulewitz et al. (6,569,145). Shmulewitz et al. discloses a pressure-controlled continuous sinus catheter.

Regarding claim 1, Shmulewitz et al. discloses a blood flow catheter comprising a catheter body (101), tip portion (103), a lumen (112), discharge opening and multiple expandable members (106A-C) that are capable of redirecting blood flow proximally along the catheter body (Figures 8-10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12 and 86 are rejected under 35 U.S.C 103(a) as being unpatentable over Berry et al. in view of Viole et al. (2002/0188167). Berry et al. meets the claim limitations as described above except an additional blood flow lumen and pump mechanism.

However, Viole et al. teaches multi-lumen recirculation catheter.

Regarding claims 9-12 and 86, Viole et al. teaches a redirecting catheter that has an additional lumen for blood removal and a pump system designed to control flow through the system (Figures 8 and 13, [0046-0047]).

At the time of the invention, it would have been obvious to add the additional lumen and pump of Viole et al. to the system of Berry et al. in order to allow for blood recirculation and proper control over this task. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Viole et al.

### ***Claim Rejections - 35 USC § 103***

Claims 14-17 are rejected under 35 U.S.C 103(a) as being unpatentable over Berry et al. in view of Hegde et al. (6,231,543). Berry et al. meets the claim limitations as described above except for the use of a guidewire lumen and seal.

However, Hedge et al. teaches a single lumen balloon catheter.

Regarding claims 14-17, Hedge et al. teaches a catheter that includes a guidewire (18) and a guidewire lumen (16) with multiple guidewire seals (30, 42, 44) that minimize blood flow through the lumen and can plug the lumen when a guidewire is not present in the lumen (Figures 4-6B).

At the time of the invention, it would have been obvious to add the guidewire and lumen of Hedge et al. to the system of Berry et al. in order to aid in catheter guiding and tracking during a surgical procedure. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the

art would have combined the teachings in the references in light of the disclosure of Hedge et al.

***Claim Rejections - 35 USC § 103***

Claims 18-20 are rejected under 35 U.S.C 103(a) as being unpatentable over Berry et al. in view of Duchamp (6,575,934). Berry et al. meets the claim limitations as described above except for a guidewire member.

However, Duchamp teaches a low profile catheter.

Regarding claims 18-20, Duchamp teaches a catheter assembly with a guidewire, guidewire lumen, and an guidewire member (80) (Figure 2).

At the time of the invention, it would have been obvious to add the add the guidewire and lumen of Duchamp to the system of Berry et al. in order to aid in catheter guiding and tracking during a surgical procedure. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Duchamp.

***Claim Rejections - 35 USC § 103***

Claims 87, 91, 95, 97, 99, 100, and 104 are rejected under 35 U.S.C 103(a) as being unpatentable over Berry et al. in view of Kurth et al. (5,792,188). Berry et al. meets the claim limitations as described above except expandable members having the properties as claimed by application regarding length and perimeter.

However, Kurth et al. teaches catheter with a balloon valve.

Regarding claims 87, 91, 95, 97, 99, 100, and 104, Kurth et al. teaches a catheter with a discharge opening that is actuated with an extensible balloon type valve that has a differing perimeter and length when expanded and also has more than one leading edge attached to the catheter body (Figure 16C).

At the time of the invention, it would have been obvious to add the balloon valve system of Kurth et al. to the system of Berry et al. because it allows for controlled opening and flow control through the discharge outlet. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Kurth et al.

### ***Claim Rejections - 35 USC § 103***

Claims 105 and 106 are rejected under 35 U.S.C 103(a) as being unpatentable over Berry et al. in view of Kurth et al.

The modified Berry et al. discloses the claimed invention except for the flaps being composed of a silicone with a material hardness of less than 15 measured on the A scale durometer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the flaps out of silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In addition it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the materials properties, since it has been held that discovering an optimum



value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 7/24/2006 have been fully considered but they are not persuasive.

Regarding the Berry et al. reference (6,293,958), Examiner asserts and maintains that in Figure 1 that expandable members (16,18) do expand and is supported by the Webster's dictionary definition (***to open up***), emphasis added:

**Main Entry: *ex·pand***

Pronunciation: ik-'spand

Function: *verb*

Etymology: Middle English *expaunden*, from Latin *expandere*, from *ex-* + *pandere* to spread -- more at FATHOM

*transitive verb*

**1 : to open up : UNFOLD**

Therefore the reference is capable of meeting applicant's claims. In addition, Applicant's representative cites cols 3: 53-54 regarding the flow turbulence created by the hinge like flaps, again, Examiner directs attention the figure being described in this citation is Figure 3, which is a substantially different embodiment to Figure 1 which is cited in the above and past rejection, the valve configurations allow for a different flow profile, which is capable of being used to directing blood flow as disclosed in the newly filed prior art Shmulewitz et al. (6,569,145). Applicant's representative asserts that Berry et al. does not disclose a blood flow lumen, which is an unsupported statement with no arguments disclosed in the currently filed remarks.

**Conclusion**

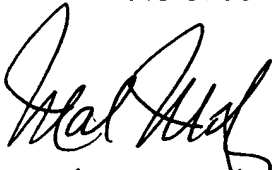
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/28/2006

  
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